(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 841 072 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
13.05.1998 Bulletin 1998/20

(51) Int. Cl.[6]: **A61M 25/00**

(21) Application number: **97119747.0**

(22) Date of filing: **11.11.1997**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **12.11.1996 US 747360**
07.11.1997 US 965776

(71) Applicant: **Stevens, Robert C.**
Williston, FL 32696 (US)

(72) Inventor: **Stevens, Robert C.**
Williston, FL 32696 (US)

(74) Representative:
Eder, Eugen, Dipl.-Ing.
Patentanwälte
Eder & Schieschke
Elisabethstrasse 34
80796 München (DE)

(54) Angiographic catheter with unitary body and tip sections and method for making same from a continuous feedstock

(57) A method of manufacturing angiographic catheters comprises providing (1) a length of elastomeric tube of a predetermined outer diameter and braiding (2) multiple strands of wire wrapping about its exterior. A plastic bonding agent is extruded (3) onto selected areas or onto the entire length of the wire wrapping to bond the strands to each other. Thereafter, the wire wrapping is ground away (4) at predetermined spaced locations along the length of the elastomeric tube to provide a series of wire wrapped sections joined by non-wrapped sections. An elastomer layer is disposed (5) over both the wire wrapped sections and the non-wrapped sections throughout the length thereof. Subsequently, the coated length is severed into pieces with the pieces each constituting unitary construction including a wire wrapped section that forms a catheter body and a non-wrapped section joined to at least one end thereof to constitute a flexible catheter tip. The angiographic catheters formed thereby include a main body portion provided with wire braiding reinforcement and a soft flexible tip portion (39, 50) having no wire braiding disposed therein.

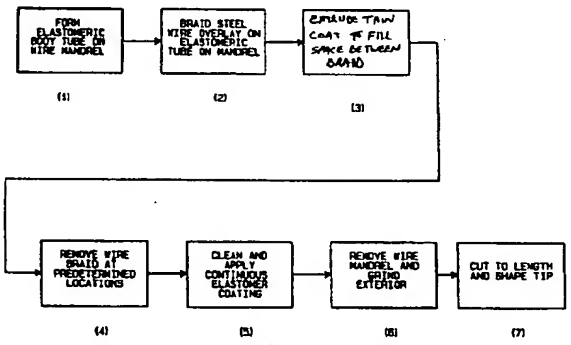

FIG. 3

EP 0 841 072 A2

BNSDOCID: <EP_____0841072A2_I_>

Description

Background of the Invention

The subject invention is directed toward the art of angiographic catheters and to catheter manufacturing methods and, more particularly, to a catheter having an improved unitary construction and to an improved method for manufacturing multiples of such catheters from a continuous feedstock.

Angiographic catheters are used for diagnostic purposes as well as for angioplasty. It is generally agreed that a good catheter should have the following features:

a) torsion control with a 1:1 rotation about its central longitudinal axis even when subjected to curvatures of as much as 110° along the catheter's length;
b) the ability to withstand high injection pressures of as much as 1000 PSI which are required where a large amount of contrast media is needed to properly visualize a given area to be studied;
c) push ability in conjunction with good torsional control along its axis mandates a catheter body having a controlled rigidity since if too rigid, it can cause injury and if too flexible, it may buckle;
d) a controlled degree of flexibility at the catheter tip is necessary to prevent injury to vessel openings and to vessel walls and this can be accomplished by using a softer plastic in this region, annular grooving, or decreasing the diameter as compared to the catheter body; and,
e) the catheter tip must be easily formed and must retain the formed shape even when subjected to straightening when passed over a guide wire.

A catheter with the above features is described in my prior U.S. Patent No. 3,485,234, which issued December 23, 1969. My prior U.S. Patent No. 3,585,707, which issued June 22, 1971, sets forth how to make or manufacture the catheter.

The catheter construction described in these prior patents uses a wire braid reinforcing to provide torsional control and to strengthen the catheter body to better withstand high pressure injections. In order to have a flexible tip with good shape memory, it is necessary that no wire braid be present in the tip area. The earlier patents describe the manner in which a tip portion is added to the catheter body. The tip portion, without braid, has heretofore been formed as a separate item which is molded or fused to the end of the catheter body. This has been the weakest portion of the catheter, since the tip may become loosened or separated over a period of time or from physical abuse such as using an oversized guide wire, severe twisting or attempts at reshaping the curvature of the tip.

The original manufacturing process used for making the original older catheters of the type described above is generally set forth in the flow chart of FIGURE 1. In particular, the process involves the following steps (the paragraph numbers correspond to the sequence numbers shown in FIGURE 1):

1) The process starts by forming a length of elastomeric tube. The tube is formed by starting with a silver plated copper wire or a monofilament of plastic (such as "Celcon" manufactured by the Hoechst Celanese Corporation, or Ultraform, an acetal copolymer manufactured by BASF), of a diameter equal to the published lumen diameter of the catheter being manufactured. This wire or monofilament is referred to as the "mandrel." As an example, a standard French 7 catheter has a lumen of .046 inches and an outside diameter of .092 inch. The wire or monofilament is purchased and used in continuous lengths of over 5000 feet. This wire or monofilament is referred to as a "mandrel" because the catheter is built on it.

The mandrel is passed through a plastic extruder, coating the mandrel with the selected elastomer to approximately .006 inch wall thickness. The elastomer or plastic used, for example, could be polyurethane containing bismuth or barium to make it opaque to x-rays, or radiopaque.

2) The coated mandrel is then placed in a "braiding machine" which overlays the elastomeric tube extrusion with multiple (e.g., 16) strands of .003 inch or smaller diameter stainless steel wire.

3) After the entire length of elastomeric extrusion has been overlaid with the wire braid, it is then cleaned in an ultrasonic cleaning bath and again passed through the plastic extruder adding another layer of plastic creating a wall thickness of approximately .012 inch. The combined layers of plastic and wire braid on the .046 inch diameter mandrel will now be approximately .094 inch in diameter.

4) Catheter tip material requires only a single extrusion on a corresponding mandrel wire because no braiding is required. The single layer of plastic applied to a .046 inch mandrel will have a wall thickness of .024 inch for a total diameter of .094 inch.

5) The body material and the tip material is cut to lengths of approximately 42 inches. This mandrel is now removed from within the cut lengths of body and tip material. This is done by stretching the mandrel, if necessary, to reduce its diameter and facilitate its withdrawal from within the plastic extrusion.

6) This material is then passed through a centerless grinder and ground to the proper diameter size and to a fine, smooth surface.

7) The tip material is then cut to lengths of approximately 3-1/2 inches and tapers are ground on one end where necessary and a flare is formed at the other end.

8) The body material is ground to a taper at one end to mate with the internal taper of the flared tip portion.

BNSDOCID: <EP_____0841072A2_I_>

9) A steel rod approximately .044 inch diameter is inserted into a catheter body and a tip is slipped onto the rod and the external taper of the body is mated with the internal taper of the tip.

10) Next, a sleeve or tube of Teflon about 6 inches in length is passed over the tip-body mated section. The tip-body with the Teflon sleeve are then pressed through a die that has been heated to approximately 325/ F. The heat plus the pressure of the sleeve fuses and mold the joined sections by melting the plastic of both parts into a smooth joint. Where necessary, the catheter assembly is again passed through the centerless grinder, particularly if the fused joint is slightly larger than the rest of the catheter. It is important that the catheter with tip be within + or -.001 inch of the published diameter.

11) The finished catheter is cut to the published length, a luer hub is added to the proximal end and the tip portion is then shaped with a forming wire in boiling water. The shapes of catheter tips are many, such as a single curve, double curve, Judkins left, Judkins right, pigtail, etc.

One major problem with the original construction of these earlier catheters is that it has been necessary to mold or fuse the tip by hand. This is very labor intensive and, therefore, expensive. In an age of rising medical costs, it is even more important than ever to reduce manufacturing costs of medical related products.

It would therefore be desirable to manufacture multiple catheters having a unitary body and soft tip construction from a single feedstock using a continuous process. Preferably, the continuous process would eliminate the need to manually mold or fuse the catheter tip to the body portion to thereby enable the desirable unitary construction. It would further be desirable to construct a unitary catheter having wire braiding in the catheter body and an absence or lack of wire braiding in the tip area.

Summary of the Invention

The subject invention greatly simplifies the process of forming catheters by eliminating several of the above-described discontinuous steps.

In addition, the process is not only simplified, but also results in a significantly better product. In particular, and in accordance with the subject invention, a first preferred method of manufacturing angiographic catheters generally comprises forming a length of cylindrical elastomeric tube of a predetermined outer diameter and braiding multiple strands of wire wrapping about the elastomeric tube. Therefore, a bonding agent is applied to the wire wrapping circumferentially thereof at spaced locations to cause the strands of wire wrapping to be bonded to each other and to the elastomer. Subsequent to the bonding, predetermined sections of the wire wrapping are removed from the elastomeric tube to leave the length of elastomeric tube with multiple wire wrapped sections spaced from one another by unwrapped sections such that each wire wrapped section has axially spaced ends enclosed by the bonding agent to prevent loosening or unwinding of the wire wrapping. Over the length of the elastomeric tube with the multiple wire wrapped sections, there is coated a continuous layer of elastomer to produce a uniform diameter length of elastomeric coated wire wrapped sections spaced from one another by unwrapped sections. The continuous length thus produced is thereafter cut transversely at locations selected to reduce the length to multiple pieces of coated wire wrapped sections each having a coated unwrapped section joined thereto at least one end thereof. The wire wrapped section of this length forms the main length and body of the catheter while the unwrapped section forms a continuous integral tip for the catheter. The tip section can, of course, be further treated to taper it and/or shape it to a desired shape. The first preferred method thus forms the main body of the catheter and the tip as a unitary structure eliminating the previously-required separate formation of the two elements following by the labor-intensive forming and bonding necessary in the prior art process.

In accordance with a second preferred method of the subject invention, the above-described step of applying the bonding agent or adhesive onto the wire wrapping circumferentially thereof at spaced locations is replaced instead with an extrusion process for uniformly coating the wire wrapping with a continuous layer of a plastic bonding agent. In particular, the second preferred method of manufacturing angiographic catheters generally comprises forming a length of cylindrical elastomeric or plastic base tube of a predetermined outer and inner diameter and braiding multiple strands of wire wrapping about the base tube. Thereafter, a thin layer of a plastic bonding agent is extruded onto the wire wrapping along the entire length of the base tube to cause the strands of wire wrapping to be bonded to each other and to the elastomer or plastic forming the base tube. Subsequent to the bonding, predetermined sections of the wire wrapping are removed from the base tube to leave the length of tube with multiple wire wrapped sections spaced from one another by unwrapped sections. Each wire wrapped section is encased by the bonding agent and has axially spaced ends enclosed by the layer of the plastic bonding agent to prevent loosening or unwinding of the wire wrapping. Over the length of the elastomeric tube with the multiple wire wrapped sections, there is then coated a continuous outer layer of elastomer to produce a uniform diameter length of elastomeric coated wire wrapped sections spaced from one another by unwrapped sections. The continuous length thus produced is thereafter cut transversely at locations selected to reduce the length to multiple pieces of coated wire wrapped sections each having a coated unwrapped section joined thereto at least one end

BNSDOCID: <EP_____0841072A2_I_>

thereof. The wire wrapped section of this length forms the main length and body of the catheter while the unwrapped section forms a continuous integral tip for the catheter. The tip section can, of course, be further treated to taper same and/or shape same to a desired shape. The second preferred method thus forms the main body of the catheter and the tip as a unitary structure eliminating the previously-required separate formation of the two elements following by the labor-intensive forming and bonding necessary in the prior art process.

The second preferred method forms a catheter with a body section having a slightly more uniform cross-section than the catheter formed according to the first preferred embodiment. In the first embodiment, the bonding agent is applied to the wire wrapping only at spaced locations along the length of the elastomeric tube, resulting in at least one pair of layering discontinuity along the length of the catheter body near the tip. The second preferred method produces a catheter without one of the layering discontinuities.

It is also contemplated that the coating of the continuous layer of elastomer over the length of elastomeric tube with the multiple wire wrapped sections will be accomplished by a conventional extruding operation.

It should be appreciated that there may be variations of the basic inventive process. The actual length in which the components are produced can also vary widely. Similarly, the orientation of the individual sections that are subsequently cut into separate and individual catheters can, of course, be varied and the types of elastomers used at various times during the process can differ.

As can be seen from the foregoing, a primary object of the invention is to provide a simplified process for forming multiple angiographic catheters from a continuous feedstock.

A still further object of the invention is to provide a method of the general type described wherein the main body of the catheter and its associated tip are formed integrally and of a unitary construction to eliminate numerous bonding and finishing steps required by the prior art processes.

Yet another object of the invention is to provide a process of the type described wherein the processing is accomplished with conventional well known types of grinding, braiding, and extruding machinery.

Still other advantages and benefits of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description.

Brief Description of the Drawings

The invention may take physical form in certain parts and arrangements of parts, the preferred embodiments of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

FIGURE 1 is a flow chart showing a typical prior art processing method used for forming angiographic catheters;

FIGURES 2a - 2e are views in side elevation of multiple catheters formed in accordance with the first preferred embodiment of the present invention from a continuous feedstock shown in various stages of sequential construction;

FIGURE 2f is a view, partially in section, of a catheter formed in accordance with the first preferred embodiment of the present invention illustrating the internal construction of the catheter tip area;

FIGURE 3 is a process chart similar to FIGURE 1 but showing the preferred processing steps according to the first and second embodiments of the present invention;

FIGURES 4a - 4e are views in side elevation of multiple catheters formed in accordance with the second preferred embodiment of the present invention from a continuous feedstock shown in various stages of sequential construction;

FIGURE 4f is a view, partially in section, of a catheter formed in accordance with the second preferred embodiment of the present invention illustrating the internal construction of the catheter tip area;

FIGURE 5 is a somewhat diagrammatic view of the preferred grinding apparatus used for removing predetermined lengths of wire wrapping from the length of elastomeric tube; and,

FIGURE 6 is a pictorial view of the preferred apparatus used for rotating the wire wrapped tube while the wrapping removal step is performed.

Detailed Description of the Preferred Embodiments

Referring now to the drawings wherein the showings are for the purposes of illustrating the preferred embodiments of the invention only and not for purposes of limiting same, in FIGURE 3, the full sequence of steps for the preferred embodiments of the inventive processes are set forth in relative diagrammatic form.

In accordance with the first preferred embodiment, and with reference now to Figures 2a-2f and 3, the method of manufacturing angiographic catheters, each having an overall length **L**, generally comprises forming a length of cylindrical elastomeric tube **10** of a predetermined outer diameter (Fig. 2a) and braiding multiple strands of fine stainless steel wire wrapping about the elastomeric tube, forming a braided tube construction **12** shown in Fig. 2b. Thereafter, a bonding agent or adhesive is applied to the braided construction circumferentially thereof at spaced locations **14, 16** and **18** as shown in Fig. 2c causing the strands of wire wrapping to be bonded to each other and to the elastomer. Subsequent to the bonding, predetermined sections of the wire wrapping are removed from the elastomeric tube to leave a length of elastomeric tube with multiple wire wrapped sections **20, 22, 24** and **26** spaced from one

BNSDOCID: <EP_____0841072A2_I_>

another by unwrapped sections **30, 32** and **34** such that each wire wrapped section **20, 22, 24** and **26** has axially spaced ends enclosed by the bonding agent (e.g., wire wrapped section **22** has axial spaced ends at the unwrapped sections **30, 32**) to prevent loosening or unwinding of the wire wrapping as best shown in Fig. 2d. A continuous layer of an elastomer is coated over the length of the elastomeric tube with multiple wire-wrapped sections to produce a uniform diameter length **36** of elastomeric coated wire-wrapped sections spaced apart from one another by unwrapped sections as shown in Fig. 2e. The continuous length thus produced is thereafter cut transversely at locations selected to reduce the length to multiple pieces of coated wire-wrapped sections having length **L**, each having a coated, unwrapped section joined thereto on at least one end thereof forming a catheter **38** having a preferred unitary construction as shown in Fig. 2f.

Turning next to FIGURES 4a-4f, the second preferred embodiment of the present invention will be described. The side elevational views of the catheter shown in FIGURES 4a - 4f in various stages of construction correspond with the manufacturing method steps illustrated in FIGURE 3. It will be noted in comparing FIGURE 3 to the prior art manufacturing process shown in FIGURE 1 and previously described above that there is no separate sequence of steps required to form tip sections. Rather, the entire sequence of steps involves a progressive processing of what is basically a single element. In particular, as shown in FIGURE 3, the process begins by the formation of an elastomeric tube **10** (FIGURE 2a) and **40** (FIGURE 4a) that has an internal open diameter that corresponds to the desired internal diameter equal to the lumen diameter of the catheter to be made. As an example, for a "French 7" size, the lumen diameter is 0.046 inches. The elastomeric body tube could be formed in other ways, but in the preferred form of the invention, it is formed by extruding a desired elastomeric material such as a relatively soft polyurethane onto a wire mandrel or onto a monofilament mandrel made of a suitable plastic having the desired lumen diameter. In the preferred embodiment illustrated, the mandrel is formed of silver plated copper.

One material that has been found to be particularly well suited for use as a catheter tube body is Pellethane, a urethane produced by Dow Chemical. In addition, other materials have been found to be adequately well suited such as nylon materials including PEBAX available from Dow Chemical. The wire can be in substantially any desired length, but is preferably a substantial number of multiples of the desired final length of the catheter being formed. As an example, I have found that it is advantageous to construct multiple catheter tube bodies onto a continuous reel of five thousand (5,000) feet of mandrel feedstock. For catheters having a nominal length of forty two (42) inches, the present invention yields up to 1,250 catheters from a single roll of feedstock.

According to the preferred manufacturing methods, the entire length, preferably five thousand (5,000) feet, of wire or monofilament which is to function as the mandrel in the formation of the basic elastomeric body tube is passed through a conventional extruder to coat the mandrel with a selected thickness, preferably of 0.006 inches, of elastomer which would vary depending upon the size of the catheter being made. Thereafter, the elastomeric tube **10, 40** (FIGURES 2a, 4a), preferably the entire five thousand (5,000) foot length, with the mandrel in place, is passed through a conventional braiding machine which overlies the elastomeric body tube with multiple strands of a small diameter stainless steel wire to form a composite braided structure **12, 42** (FIGURES 2b, 4b). For example, it is common to use 16 strands of .003 inch diameter stainless steel wire which is braided onto the elastomeric body tube in the manner discussed in my prior U.S. Patent No. 3,585,707 which is incorporated herein by reference.

Thereafter, the entire length, in the preferred embodiments illustrated five thousand (5,000) feet, of the braided overlay is coated with a suitable coating capable of bonding the wire elements on the braided body together. In the first preferred embodiment, selected portions of the braided overlay are coated as described above. In the second preferred embodiment, the entire length of braided overlay is coated with a continuous suitable braiding agent as will be described in greater detail below. These steps form a coated braided composite structure **13, 44** (FIGURES 2c, 4c). Epoxy coatings have been used for this purpose as well as coatings that are UV curable. However, those coatings must be applied with rollers, brushed on, or sprayed. It is important that only enough epoxy or other adhesives be applied to fill the interstices of the wire braid and onto the base coating. This is hard to control using coatings. In the preferred form according to the present invention therefore, the coating for bonding the braid to the body tube is extruded onto the entire length of the feedstock carrying the elastomeric body tube with the braided overlay.

According to the present invention the coating is preferably a plastic material such as Pellethane which is a urethane produced by Dow Chemical. Alternatively, however, a nylon material can be used such as PEBAX. I have found that the thermal properties of these materials enable them to be extruded, one plastic upon another plastic, without the first plastic layer being scraped away in the guider tip of the extruder nozzle. In that manner the entire base coat comprising the catheter tube body is extrudable through the extruder tip for the formation of a second layer of plastic extrusion directly onto the braided catheter body tube. In the preferred embodiments, the secondary layer of plastic extrusion material is formed to a thickness of 0.003 inches upon the braided overlay. Although the secondary plastic coating is thin, it penetrates between the strands of wire braid and mechanically locks the stain-

BNSDOCID: <EP_____0841072A2_I_>

less steel wires in place so that they do not unravel during the grinding operation described below.

Subsequent to the plastic or epoxy coating in the manner described above, the length of braided and epoxy coated stock is treated so as to remove approximately 3-1/2 inches (length of soft tip portion) of braided material every 42 inches (overall length of catheter) for the entire length of feedstock. This forms a composite cylindrical tube **19, 46** (FIGURES 2d, 4d) with multiple wire wrapped sections spaced from one another by unwrapped sections. The plastic or epoxy holds the remaining braided sections in place and prevents unraveling. Preferably, and in accordance with the preferred embodiment, the braid is removed by a grinding operation. The depth of the grind is approximately .006 inch so that the braiding is removed down to the base coat which is the formed elastomeric tube formed in the first step. The present invention is adapted to construct catheters having any overall length by merely spacing apart the ground area by more or less than 42 inches. In addition, various catheter tip lengths are constructed by grinding more or less than 3-1/2 inch areas of wire braid.

Centerless grinders are widely used in industry and in angiographic catheter manufacture in particular. Catheter stock is "fed" though the grinder to remove excess plastic and to bring it to an accurate diameter. The grinder also creates a smooth surface finish. Centerless grinders are also used to grind tapers on catheter tips.

In centerless grinding, the machine weighs over 1000 pounds. This helps to give it great accuracy (+ or - .0001 inch). The grinding wheel used in catheter production can be 6-8 inches in diameter with a width of 4 inches or greater. Perfect balancing is mandatory.

In centerless grinding, the part to be ground must be rotated under the grinding wheel, This is not a problem where the part is inches or even a few feet in length. However, where the part to be ground is 5000 feet or longer, this is not very satisfactory. With 5000 feet of braided catheter material on a spool weighing 50 pounds or more, it is not generally practical to rotate the spool at speeds of at least 200 RPM. Not only would you have to rotate the spool, but also feed off sections of braided material every 42 inches as you rotate.

In order to rotate the catheter stock during grinding and use the standard heavy but accurate centerless grinders currently available, I have devised a means to rotate only the portion of the catheter stock to be ground.

Referring in particular to FIGURES 5 and 6, my preferred form of grinding apparatus can be understood. Specifically, the grinder **90** is a centerless grinder modified by the addition of a motor driven clamping device **102** having a releasable collet **104** which firmly grips the wire braided stock at a point adjacent to where grinding is to begin and rotates, for example, 360° clockwise, then 360° counterclockwise to expose the entire circumference of the wire braided area to be removed by the grinder. The grinder **90** includes an upper grinding wheel **91** and a support wheel **93** arranged to engage on opposite sides of the catheter stock **92** passing therebetween. The operation and control of the grinder is well known.

The device **102** (see FIGURE 6) is driven by motor **106** with a crank arm **108** attached to an output shaft **110** of the motor. The crank arm **108** is connected with a connecting rod **112** that drives a rack gear **114** which rotates a pinion **116**. The catheter stock **92** passes through the center of the pinion **116**. The pinion is attached to a rotatably mounted shaft **118** that supports collet **104**, which firmly grips the catheter stock **92** at a point adjacent to where grinding is to begin. As the rack gear **114** moves back and forth, a reciprocating back and forth motion of the collet is generated. A rate of about 200 RPM for shaft **118** has been found satisfactory.

After the braid has been removed in the desired areas, the braided and non-braided continuous section of stock is run through a plastic extruder and the finished coat of elastomer applied to a uniform diameter throughout the entire length of base stock resulting in the alternate sections of braid reinforced and non-braided sections being covered by an outer jacket **36, 48** (FIGURES 2e, 4e). Subsequently, the wire mandrel is removed. Thereafter, the entire length of catheter material is ground to have the desired final exterior catheter diameter with a proper surface smoothness. This is a known form of grinding using a centerless grinder. The catheter sections are cut to length which results in a main wire reinforced body and a 3-1/2 inches non-reinforced tip portion. The tip portions **39, 50** (FIGURES 2f, 4f) can be subsequently tapered and/or shaped as desired. Additionally, thereafter, hub or other elements are added to the catheter body, as needed.

As can be seen, the described method can be varied widely. It is important to note, however, that the labor-intensive problems involved with attaching a separate tip to a wire braid reinforced catheter body are totally eliminated by the subject processing. Also, the discontinuous operation of laying multiple spaced apart circumferential epoxy bands onto the elastomeric tube has been eliminated. Additionally, grinding the joint between the tip and the body is eliminated. This elimination of the added steps and labor results in a less expensive catheter construction. In addition to reduced labor costs, the resulting catheter is significantly better because the possibility of failure at a bonded section are totally eliminated.

The invention has been described with reference to the preferred embodiment. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. It is intended to include all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

BNSDOCID: <EP_____0841072A2_I_>

Claims

1. A method of manufacturing angiographic catheters comprising:

providing a length of cylindrical elastomeric tube having a predetermined inner diameter;
braiding multiple strands of wire wrapping about said elastomeric tube;
applying a bonding agent onto the wire wrapping to bond the strands of wire wrapping to each other and to the elastomeric tube;
removing predetermined sections of wire wrapping from about the elastomeric tube to leave said length of elastomeric tube within multiple wire wrapped sections spaced from one another by unwrapped sections;
coating a continuous outer layer of elastomer over said length of elastomeric tube with multiple wire wrapped sections spaced from one another by unwrapped sections; and,
cutting the coated length of elastomeric tube with multiple wire wrapped sections spaced from one another by unwrapped sections transversely at locations selected to reduce said length to multiple pieces of coated wire wrapped sections each having a coated unwrapped section joined thereto on at least one end thereof.

2. The method of manufacturing angiographic catheters according to claim 1 wherein:

the step of braiding said multiple strands of wire wrapping about said elastomeric tube includes braiding said multiple strands of wire wrapping onto the entire length of said elastomeric tube;
the step of applying said bonding agent onto the wire wrapping includes extruding said bonding agent onto the wire wrapping for the entire length of said elastomeric tube; and,
the step of coating said continuous outer layer of elastomer over said length of elastomeric tube includes extruding said continuous outer layer of elastomer onto the multiple wire wrapped sections spaced apart from one another by unwrapped sections for the entire length of said elastomeric tube.

3. The method of manufacturing angiographic catheters according to claim 1 wherein:

the step of applying said bonding agent onto the wire wrapping includes applying, onto the wire wrapping, circumferentially extending bands of said bonding agent at spaced locations; and,
the step of removing predetermined sections of the wire wrapping includes removing predetermined sections of the wire wrapping from about the elastomeric tube to leave said length of elastomeric tube with said multiple wire wrapped sections spaced from one another by said unwrapped sections, each said wire wrapped section having axially spaced ends enclosed by said bonding agent disposed onto the wire wrapping in the applying step.

4. The method of manufacturing angiographic catheters according to claims 2 or 3 wherein the step of removing said predetermined sections of the wire wrapping includes grinding said predetermined sections of the wire wrapping from about the elastomeric tube to leave said length of elastomeric tube with said multiple wire wrapped sections spaced from one another by said unwrapped sections.

5. The method of manufacturing angiographic catheters according to claim 4 wherein:

the step of providing said length of cylindrical elastomeric tube includes extruding a first plastic material over a plastic or wire mandrel to form said elastomeric tube; and,
the plastic or wire mandrel is removed from within the elastomeric tube after said coating step.

6. An angiographic catheter manufacturing according to any of the methods of claims 1-5.

7. An angiographic catheter comprising:

in a body portion of the angiographic catheter:

a first portion of an elongate cylindrical tube, the elongate cylindrical tube having a predetermined inner diameter and the first portion of the elongate cylindrical tube having a first overall length;
multiple strands of wire wrapping braided onto said first portion of said elongate cylindrical tube substantially along said first overall length;
a bonding agent bonding said multiple strands of wire wrapping to said first portion of said elongate cylindrical tube; and,
a finish coating on said bonding agent substantially entirely along said first overall length; and

in a tip portion of the angiographic catheter:

a second portion of said elongate cylindrical tube; and,

BNSDOCID: <EP_____0841072A2_I_>

a layer of said finish coating disposed directly onto said second portion of said elongate cylindrical tube.

8. The angiographic catheter according to claim 7 wherein said bonding agent is disposed substantially entirely along said first overall length of said first portion of the elongate cylindrical tube for bonding said multiple strands of wire wrapping to said first portion of the said elongate cylindrical tube.

9. The angiographic catheter according to claim 7 wherein said bonding agent is disposed in predetermined areas along said first overall length of said first portion of said elongate cylindrical tube for bonding predetermined portions of said multiple strands of wire wrapping to said first portion of said elongate cylindrical tube.

10. The angiographic catheter according to claim 9 wherein said bonding agent is disposed substantially entirely along said first overall length of the first portion of the elongate cylindrical tube in a regular repeating spaced apart pattern.

BNSDOCID: <EP_____0841072A2_I_>

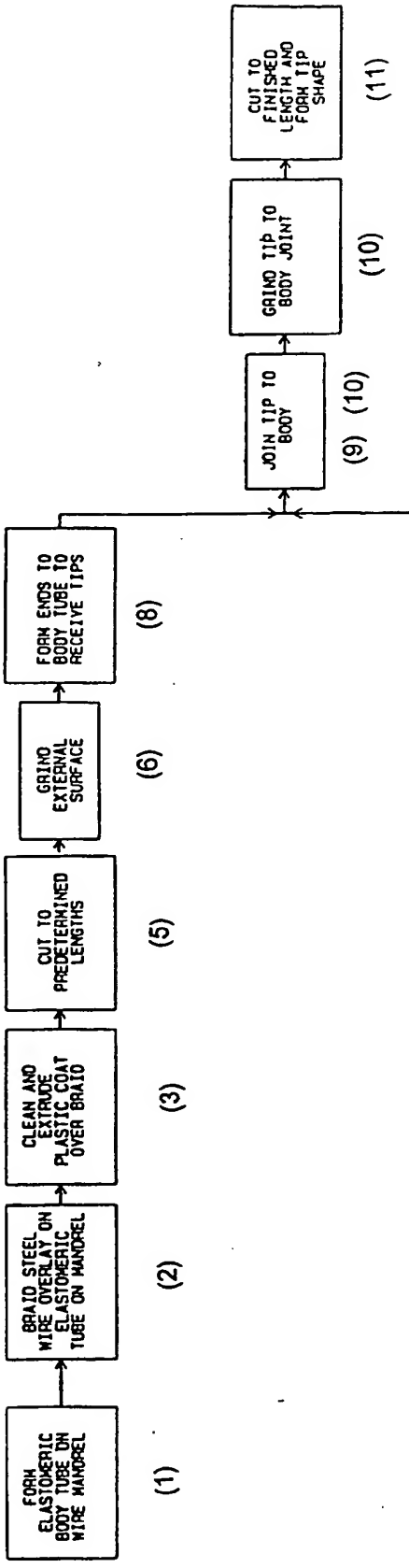

FIG. 1
(Prior Art)

BNSDOCID: <EP_____0841072A2_I_>

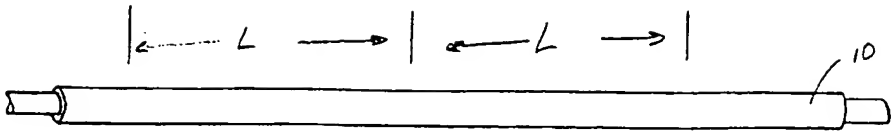

FIG. 2a

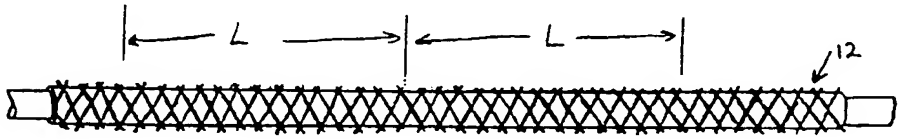

Fig. 2b

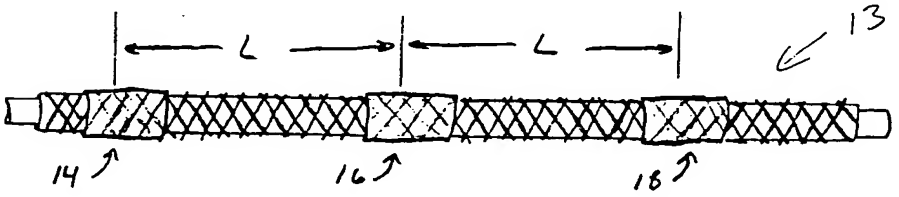

Fig 2c

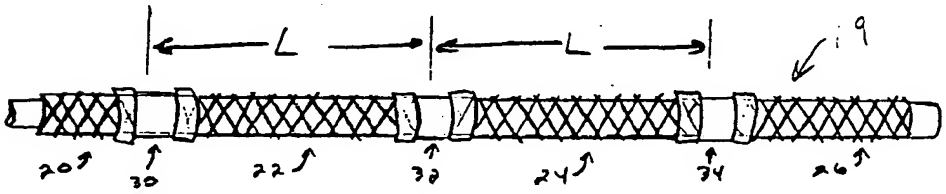

FIG. 2d

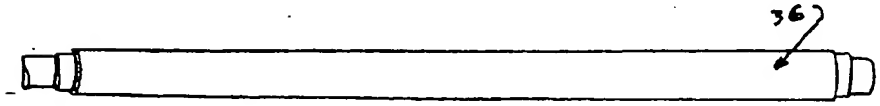

FIG. 2e

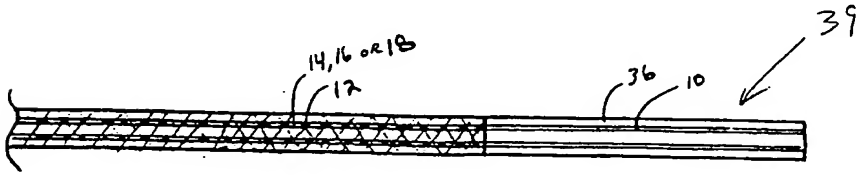

FIG. 2f

BNSDOCID: <EP_____0841072A2_I_>

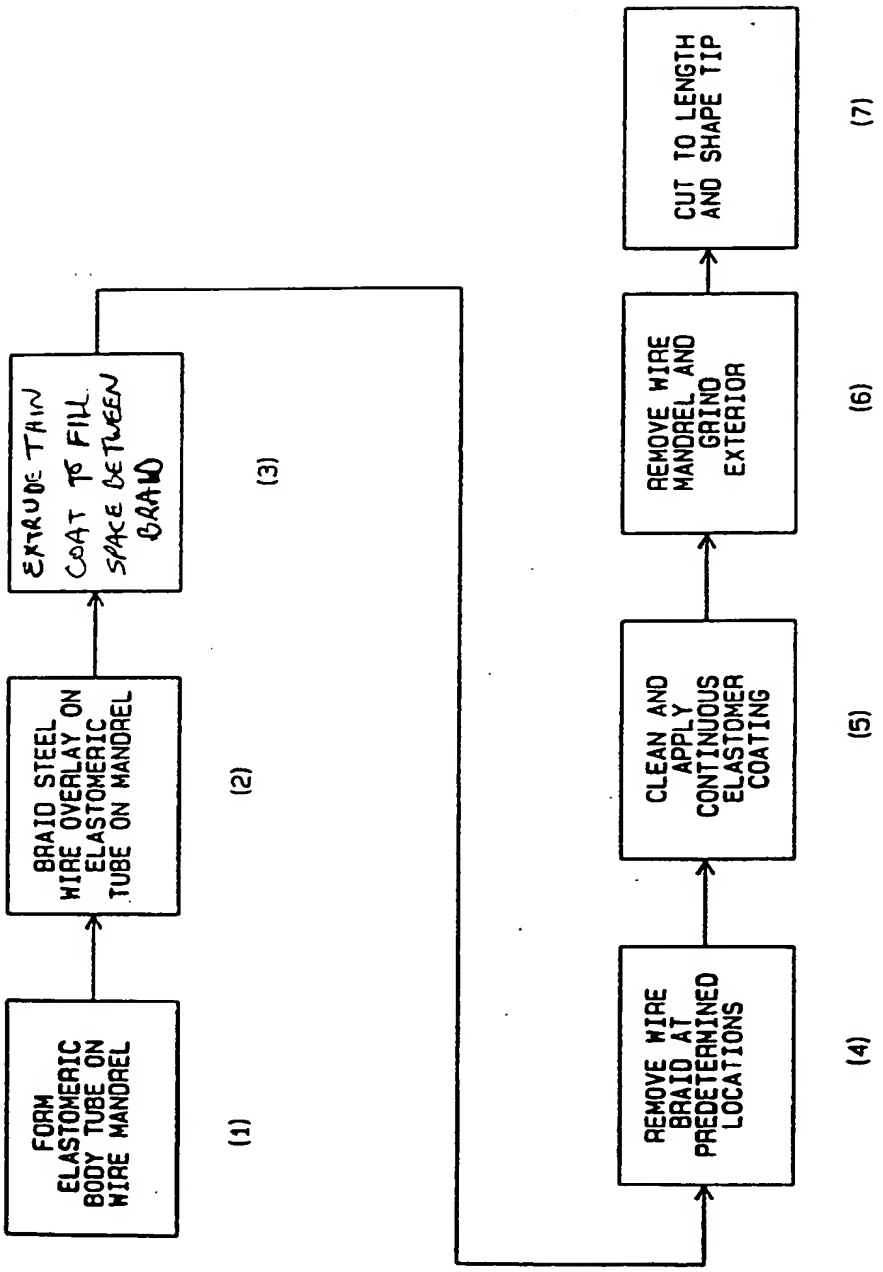

FIG. 3

BNSDOCID: <EP_____0841072A2_I_>

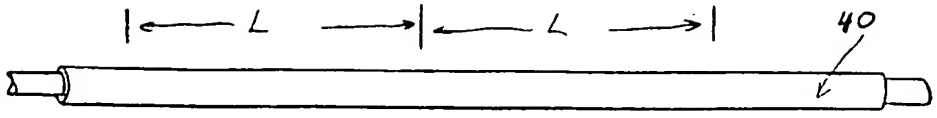

FIG. 4a

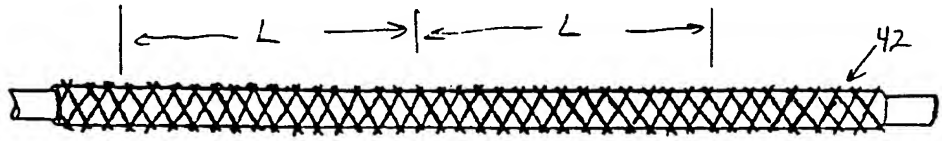

FIG. 4b

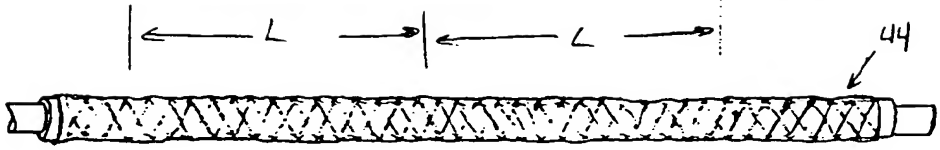

FIG. 4c

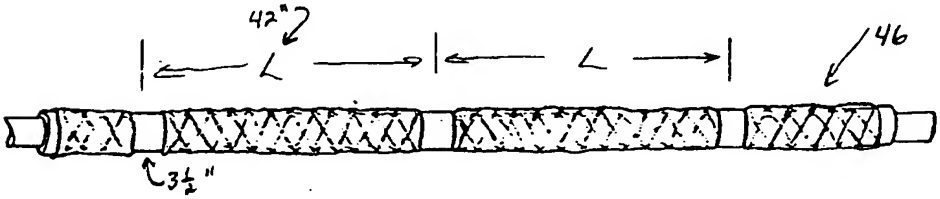

Fig. 4d

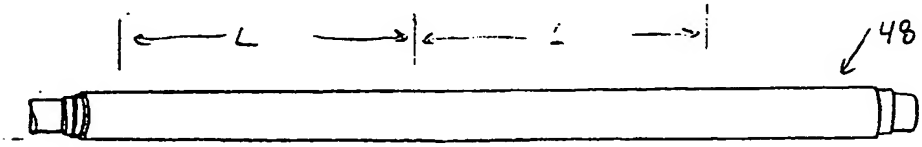

Fig. 4e

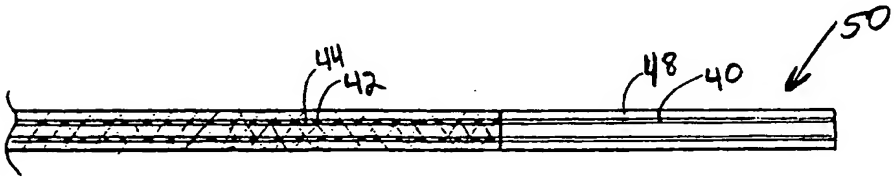

FIG. 4f

BNSDOCID: <EP_____0841072A2_I_>

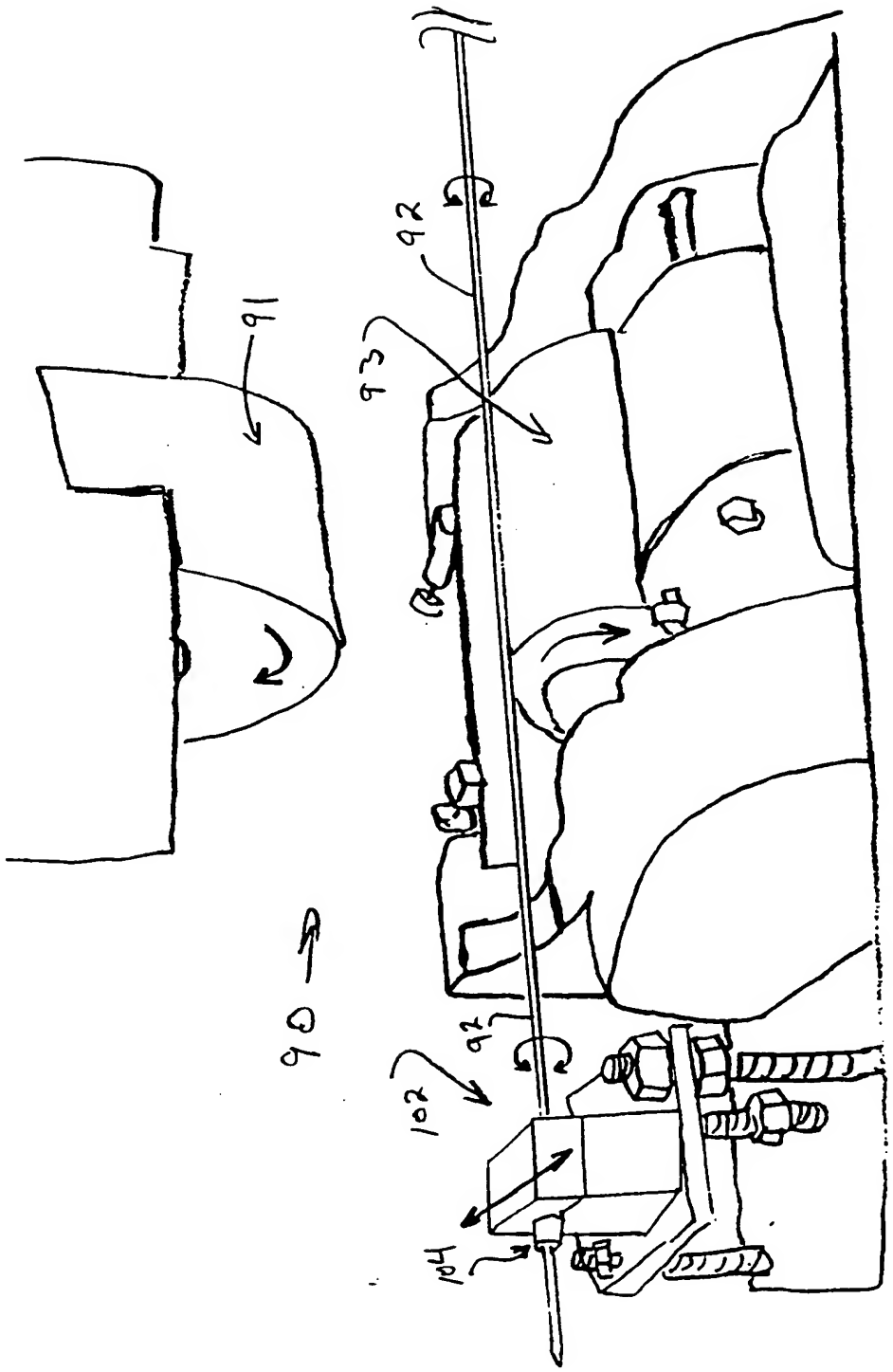

FIG. 5

BNSDOCID: <EP_____0841072A2_I_>

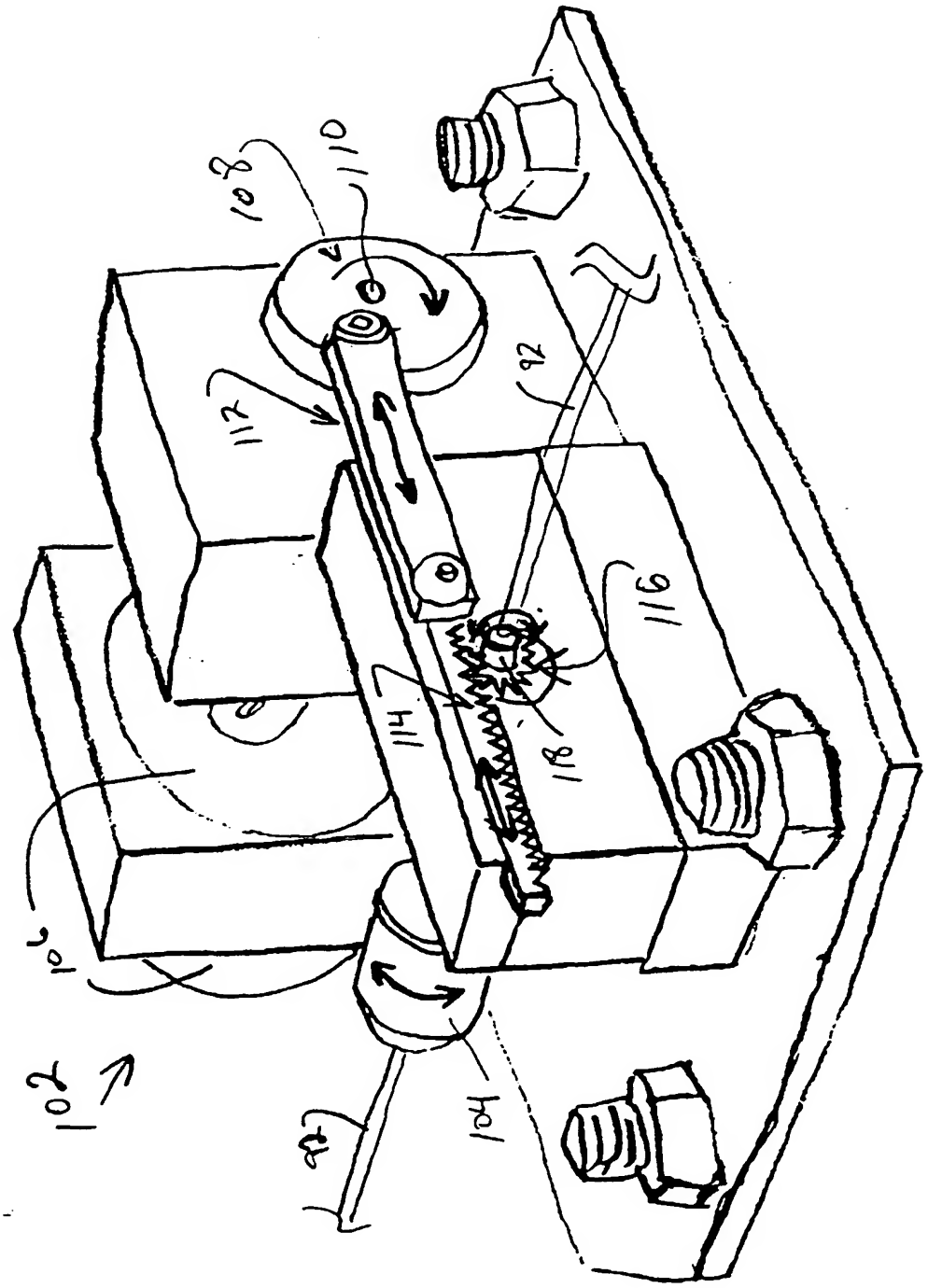

FIG. 6

BNSDOCID: <EP_____0841072A2_I_>

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 841 072 A3

(12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
12.08.1998 Bulletin 1998/33

(43) Date of publication A2:
13.05.1998 Bulletin 1998/20

(21) Application number: **97119747.0**

(22) Date of filing: **11.11.1997**

(51) Int. Cl.[6]: **A61M 25/00**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **12.11.1996 US 747360**
07.11.1997 US 965776

(71) Applicant: **Stevens, Robert C.**
Williston, FL 32696 (US)

(72) Inventor: **Stevens, Robert C.**
Williston, FL 32696 (US)

(74) Representative:
Eder, Eugen, Dipl.-Ing.
Patentanwälte
Eder & Schieschke
Elisabethstrasse 34
80796 München (DE)

(54) Angiographic catheter with unitary body and tip sections and method for making same from a continuous feedstock

(57) A method of manufacturing angiographic catheters comprises providing (1) a length of elastomeric tube of a predetermined outer diameter and braiding (2) multiple strands of wire wrapping about its exterior. A plastic bonding agent is extruded (3) onto selected areas or onto the entire length of the wire wrapping to bond the strands to each other. Thereafter, the wire wrapping is ground away (4) at predetermined spaced locations along the length of the elastomeric tube to provide a series of wire wrapped sections joined by non-wrapped sections. An elastomer layer is disposed (5) over both the wire wrapped sections and the non-wrapped sections throughout the length thereof. Subsequently, the coated length is severed into pieces with the pieces each constituting unitary construction including a wire wrapped section that forms a catheter body and a non-wrapped section joined to at least one end thereof to constitute a flexible catheter tip. The angiographic catheters formed thereby include a main body portion provided with wire braiding reinforcement and a soft flexible tip portion (39, 50) having no wire braiding disposed therein.

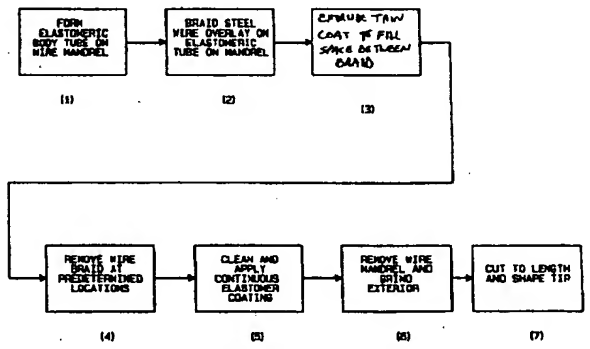

FIG. 3

EP 0 841 072 A3

BNSDOCID: <EP_____0841072A3_I_>

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 11 9747

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	FR 2 454 907 A (SURGIMED) 21 November 1980 * page 3, line 6 - line 31 * * page 5, line 18 - line 37 * * claim 12 * * figure 1 *	1,6,7	A61M25/00
Y	US 4 577 543 A (WILSON) 25 March 1986 * column 1, line 14 - line 20 * * column 1, line 46 - line 56 * * column 2, line 44 - line 47 * * column 4, line 29 - line 42; claim 8 * * figures 1,2 *	1,6,7	
A	EP 0 086 498 A (CORDIS) 24 August 1983 * page 2, line 21 - page 3, line 3 * * figures 3-5 *	1,6,7	
A	US 3 988 189 A (SULLIVAN) 26 October 1976 * abstract * * column 2, line 10 - line 35 * * figure 5 *		TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	US 3 945 867 A (HELLER, LEATHERMAN) 23 March 1976 * abstract * * column 2, line 48 - column 3, line 5 * * column 3, line 15 - line 31 * * figures 4A-4D * * figure 5 *		A61M F16L B29C

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 June 1998	Mary, C

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

BNSDOCID: <EP_____0841072A3_I_>